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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,451	12/03/2003	Shingo Kakuo	246089US0	4055

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EXAMINER

LEITH, PATRICIA A

ART UNIT PAPER NUMBER

1655

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/725,451

Applicant(s)

KAKUO ET AL

Examiner

Patricia Leith

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2005.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-3 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-3 are pending in the application and were examined on the merits.

Election/Restrictions

Applicant's election of the species of cucumber in the reply filed on 7/25/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 U.S.C. 101 because it is directed, in part, toward a product of nature; a cucumber. Correction is necessary.

Claim Rejections - 35 USC § 112

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-3 recite 'extract'. It is deemed that Applicant has not set forth a representative number of examples in order to reasonably verify possession of such a potentially enormous number of extracts.

Although Applicant has disclosed what appears to be many solvents which could potentially be used to extract cucumber, this is actually a very few number in comparison to the enormous, potentially millions of types of extracts which could be obtained from cucumber. The reason for this large amount of permutations is because extraction techniques are often coupled in order to obtain a product; for example

1) a water extraction followed by an alcoholic extraction: the product obtained is an extract.

2) a supercritical extraction (CO_2) followed by an alcoholic and then a non-polar solvent extraction (e.g., chloroform): the product is an extract.

3) a benzene extraction followed by a water extraction and chromatographic separation: the product is an extract.

4) a water/chloroform extraction (e.g., in a separatory funnel), followed by collection of the water layer, chromatographic separation and crystallization of an isolate: the product is an extract.

5) squeezing the cucumber to obtain a juice: the product is an extract.

6) dipping the cucumber in an organic solvent to remove the waxy layer: the product is an extract.

Therefore, it is deemed that Applicant was not in possession of a reasonable number of potential extracts of cucumber and therefore the rejection is proper.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites 'a plant selected from among mulberry...and phellodendron bark; or chlorella or an extract of any of these ingredients'. This is deemed to be an improper Markush group because of the recitation of 'and phellodendron bark; or chlorella; or an extract'. The wording is confusing in that it cannot be ascertained if chlorella and extract are part of the 'group'. Also, regarding this Markush group, it is deemed that 'mulberry bark and 'phellodendron bark' lack antecedent basis because the claim previously recited 'plant' and not 'plant parts' (thus, this phrase lacks antecedent basis as well as provides another condition for improper Markush practice). Further, it is not absolutely clear what 'these ingredients' on line 4 of the claim is referring to; thus, this phrase lacks clear antecedent basis.

Claim 2 also recites 'a plant selected from among mulberry...and phellodendron bark; or chlorella or an extract of any of these ingredients'. . This is deemed to be an improper Markush group because of the recitation of 'and phellodendron bark; or chlorella; or an extract'. The wording is confusing in that it cannot be ascertained if chlorella and extract are part of the 'group'. Also, regarding this Markush group, it is deemed that 'mulberry bark and 'phellodendron bark' lack antecedent basis because the claim previously recited 'plant' and not 'plant parts' (thus, this phrase lacks

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antecedent basis as well as provides another condition for improper Markush practice).

Further, it is not absolutely clear what 'these ingredients' on line 4 of the claim is referring to; thus, this phrase lacks clear antecedent basis.

Claim 3 also recites 'a plant selected from among mulberry...and phellodendron bark; or chlorella or an extract of any of these ingredients'. This is deemed to be an improper Markush group because of the recitation of 'and phellodendron bark; or chlorella; or an extract'. The wording is confusing in that it cannot be ascertained if chlorella and extract are part of the 'group'. Also, regarding this Markush group, it is deemed that 'mulberry bark and 'phellodendron bark' lack antecedent basis because the claim previously recited 'plant' and not 'plant parts' (thus, this phrase lacks antecedent basis as well as provides another condition for improper Markush practice). Further, it is not absolutely clear what 'these ingredients' on line 4 of the claim is referring to; thus, this phrase lacks clear antecedent basis.

Claim Rejections - 35 USC § 112/101

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 provides for the use of a plant, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Because it cannot be clearly determined what Applicant intends to claim, this claim has not been further treated on the merits.

Claim 2 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Bolton (US 1,687,154).

Bolton (US 1, 687, 154) taught a food product comprising cucumber pickles (see claim 1 for example). Thus, the cucumber fruit was well known and consumed in this country at the time the Instant invention was made.

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Swain (1998).

Swain (1998) reported that because foods such as cucumber contain phytoestrogens "similar to human sex hormones", that these foods can be used to treat menopause (see p. 1). It is well known that during menopause, estrogen levels in women are naturally declined.

It is noted that claim 3 states 'prevention'. It is deemed that because people (including women) ate cucumber at the time the Invention was made, that eating cucumbers would have inherently produced the claimed results because the only step in the method is administration of a cucumber.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swain (1998).

The teachings of Swain (1998) were taught supra. Swain did not specifically teach the treatment of lesions due to estrogen deficiency via the use of cucumbers.

One of ordinary skill in the art would have been motivated to eat cucumber during menopause (concurrently during a period of lowered estrogen levels) because eating cucumbers contain phytoestrogens which will beneficially treat symptoms of menopause such as hot flashes (p.1).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

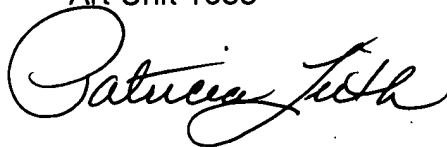
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Leith
Primary Examiner
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A handwritten signature in cursive script, appearing to read "Patricia Leith", is written over the typed name and title.

8/11/05